REMARKS

Applicants respond hereby to the Official Action mailed September 22, 2004, from the USPTO. A Petition for extension of time accompanies this Amendment, extending the time for response hereto up to and including January 22, 2005.

Claims 1, 2, 5, 6, 7, 8, 9, 13 and 15 are amended hereby to address the informalities set forth by the Examiner in the "Claim Objections" portion of the outstanding Office action, and to place the claims in better form. No new matter has been added.

Rejection Under 35 USC § 102

In the outstanding Office Action, claim 15 was rejected under 35 USC § 102(b) as anticipated by US Patent No. 6,076,005 to Sontag, et al. (Sontag). The Examiner asserts that Sontag generates a respiratory signal representing the flow of gas into and out of the subjects lungs during the breathing cycle (col. 5, ll. 34-38); and wherein the trigger generator 16 calculates a differential of the respiratory signal (using a differential pressure pneumotachometer) and generates a trigger signal when the differential has a value representing a selected point in the subjects breathing cycle (col. 5, l. 36, and tables 1-3).

Applicants respectfully disagree.

Applicants independent claim 15 sets forth a trigger generator for supplying a trigger signal to a medical device. The trigger generator includes a respiratory signal device associated with the subject that generates a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathing cycle. The trigger generator calculates a differential of the respiratory signal and generates the trigger signal when the differential of the respiratory signal has a value representing a

selected point in the subject's breathing cycle.

Sontag teaches a system for gating energy to a tissue volume during a selected portion of a patient's respiratory cycle. At col. 5, Sontag's system 8 is shown to include a respiratory monitor 10, used to categorize respiratory mechanics of the patient 15, and includes a differential pressure pneumotachometer for measuring airway pressure and calculating airway flow and lung volume. The pneumotachometer generates signals representative of flow, pressure, lung volume and Carbon dioxide content. Sontag seeks the point of maximum exhalation as the trigger point, where the carbon dioxide is greater than a set point and the volume is less than a set point, or maximum inhalation, where exhalation is preferred.

Sontag does not teach or suggest generating a respiratory signal representing the flow of gas *into* **and** *out* of the subject's lungs during the subject's breathing cycle. Nor does the Sontag trigger generator calculate a differential of the respiratory signal, and generates the trigger signal based on the differential of the respiratory signal, as required by applicants' claim 15. Sontag may use a differential pressure pneumotachometer, to calculate airway flow pressure and volume, but does not perform and differentiation of a respiratory signal and compare it to a set value to facilitate improved triggering, as does claim 15.

Accordingly, applicant respectfully asserts that claim 15 is patentably distinct from Sontag under 35 USC § 102(b), and requests withdrawal of the rejection of claim 15 thereunder.

Rejection Under 35 USC § 103

In the outstanding Office Action, claims 1-14 were rejected under 35 USC § 103(c) as anticipated by Sontag in view of US 4,368,740 to Binder (Binder).

With respect to independent claims 1, 4, 7 and 8, the Examiner asserts that Sontag teaches a trigger generator and method for supplying a trigger signal including a respiratory signal device 10, wherein the trigger device generates a trigger signal when the respiratory signal with a value representative to a selected point in the respiratory cycle (col. 5, ll 55-58, and col. 8, ll. 22-24). While the Examiner indicates that Sontag does not disclose that trigger generator 16 integrates a flow signal, he asserts that it is well known in the art to integrate a flow signal to obtain a volume signal, and that Binder teaches using a differential pneumotachometer 6 to measure respiratory flow and integrate the flow signals to realize volume signals, that Sontag uses volume to generate trigger signals, rendering applicant's independent claims 1, 5, 7 and 8 obvious.

Applicants respectfully disagree.

Applicants' claim 1 sets forth a trigger generator for supplying a trigger signal to a medical device. The trigger generator includes a respiratory signal device associated with a subject that generates a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathing cycle. The trigger generator includes an integrator that integrates the respiratory signal to form an integrated respiratory signal, and generates the trigger signal when the integrated respiratory signal has a value representing a selected point in the subject's breathing cycle.

Applicants' claim 2 sets forth a method for triggering operation of a medical system at a selected point in a subject's breathing cycle. The method includes receiving a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathing cycle, integrating the respiratory signal to create an integrated respiratory signal and triggering the medical device when the integrated respiratory signal has a value corresponding to a selected point in the

subject's breathing cycle.

Applicants claim 7 sets forth a trigger generator for supplying a trigger signal to a medical device. The trigger generator includes respiratory signal means associated with a subject for generating a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathing cycle, and integrating the respiratory signal to generate an integrated respiratory signal, as well as trigger generator means for integrating the respiratory signal and generating the trigger signal when the integrated respiratory signal has a value representing a selected point in the subject's breathing cycle.

Applicants' claim 8 sets forth a medical data acquisition system with a medical data system that acquires a set of data from a subject based on a trigger signal, a respiratory signal device associated with the subject that generates a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathing cycle and a trigger generator that integrates the respiratory signal to generate an integrated respiratory signal and generates the trigger signal when the integrated respiratory signal has a value representing a selected point in the subject's breathing cycle.

With respect to each of claims 1, 4, 7 and 8, Sontag does not teach or suggest generating a trigger signal when a single respiratory signal has a value representing a single place in the respiratory cycle, still less an integrated respiration signal. Applicants' respiratory signal represents the flow of gas into and out of the subject's lungs. Binder includes activity detector 25 for resetting a reset flow indictor for use in the Binder algorithm. It looks to the expiratory flow signal corresponding to completion of expiratory flow. Binder's expiratory flow integrator 23 samples and integrate expiratory flow signal 8 to get a signal proportional to flow volume. Again, Binder does not teach or

suggest a respiratory signal representing the flow of gas **into and out of** the subject's lungs **during** the subject's breathing cycle, nor a trigger generator that includes an integrator for integrating such a respiratory signal to form an integrated respiratory signal, where the integrated respiratory signal is the basis for the point in the complete respiration cycle for triggering.

Hence, even combining Sontag with Binder (assuming arguendo that there is a reason for doing same) would still not render obvious applicants' inventions as claimed.

Accordingly, applicants respectfully assert that claims 1, 4, 7 and 8 are patentable under 103(c) in view of the Sontag/Binder combination for at least the reasons set forth. For that matter, applicants further assert that dependent claims 2, 3, 5, 6, 9 and 10-13 are also patentable under 103(c) in view of the Sontag/Binder combination for at least the reasons set forth e patentability of claims 1, 4, 7 and 8, and respectfully requests withdrawal of the rejections to all of claims 1-13 under 103(c).

With respect to claim 14, the Examiner asserts that Sontag teaches a trigger generator for supplying a trigger signal based on a respiratory signal representing gas flow into and out of a subject's lungs, but not an integrator. The Examiner states, however, that it is well known in the art to integrate a flow signal from a pneumotachometer to obtain volume signals, such as Binder's integrator 23 (col. 4, l 67 to col. 5, l. 3), rendering claim 14 obvious.

Applicants respectfully disagree. What the Examiner refers to as flow integrator 23 is actually an expiratory flow integrator, which samples and integrates expiratory flow signal 8 to determine volume of expired gas from the lungs. Accordingly applicants respectfully assert that claim 14 is not obvious in view of Sontag, whether alone or in combination with Binder, for at least the reasons set forth above for the patentability of claims 1, 4, 7 and

8, and request withdrawal of the rejection of claim 14 under 35 USC 103(c) based thereunder.

Applicants' undersigned attorney may be reached at the number listed below and would welcome a telephone call from the Examiner to discuss the instant merits in order to further the prosecution and passage to issue of this application.

Respectfully submitted,

By_____
John F. Vodopia, Reg. 36,299
Attorney For Applicants
(914) 333-9641